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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,558	03/30/2001	Stefan Spiess	4271-30PUS	1486

7590 12/31/2003

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EXAMINER	
TATE, CHRISTOPHER ROBIN	
ART UNIT	**PAPER NUMBER**
1654	18

DATE MAILED: 12/31/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/806,558	Applicant(s) Spiess
	Examiner Christopher Tate	Art Unit 1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jul 22, 2003 and Aug 4, 2003* .

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *15-40* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *15-40* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 22, 2003 has been entered. In addition, the August 4, 2003 request and subsequent approval for a three-month suspension of action is noted.

Claims 15-40 are presented for examination on the merits. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 U.S.C. § 112

Claims 16 and 28 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 remains vague and indefinite by the phrase "wherein at least one of the components is in the form of a preparation of a pharmaceutically active ingredient" (lines 2-3). It is totally unclear as to what this phrase is defining - e.g., claims 15 and 16 are already drawn to an herbal pharmaceutical preparation so how is the at least one component in the form of a "preparation"; also, all of the recited components would be expected to be active pharmaceutical ingredients, so how does this further limit the definition of such components?

Claim 28 remains unclear by the phrase "of menstrual complaints or of additional gastrointestinal complaints" - e.g., it is unclear if the gastrointestinal complaints are associated with the menstrual complaints or if they are in addition to something else. Applicants' arguments have been carefully considered but are not deemed to be persuasive of error in the rejection. Applicants argue that one of skill in the art would understand "additional gastrointestinal complaints" refers to other conditions because there may be stomach pain from other conditions than menstrual cramps. Again, it is unclear by this argument as to what is meant by the above phrase - i.e., are the gastrointestinal complaints associated with the menstrual complaints or not?

Claim Rejections - 35 U.S.C. § 102

Claims 15-17, 21, 22, 27, 29, and 34 stand rejected under 35 U.S.C. 102(b) as being anticipated by the Product Alert Bulletin regarding Alvita Herbal RemeTeas (22 July 1996 - PROMT Abstract) for the reasons set forth in the previous Office action, which are restated below.

The Product Alert Bulletin discloses a commercial product from Alvita Herbal RemeTeas called Migra-Wonder™ which comprises feverfew and ginger and which, as the name clearly implies, is used to treat headaches including migraine headaches (see abstract).

Therefore, the reference is deemed to anticipate the instant claims above.

Applicants' previous arguments with respect to the above U.S.C. 102 rejection have been carefully considered but are not deemed to be persuasive of error in the rejection. Applicants appear to argue that Product Alert Bulletin does not necessarily teach a preparation comprising a combination of *Tanacetum parthenium* (feverfew) and one of the other claimed components (i.e., *Zingiber officinale* - aka ginger), and that applicants request that examiner make of record the entirety of this article. However, this full-text enabled abstract expressly teaches such a combination as an anti-migraine preparation.

Claim Rejections - 35 U.S.C. § 103

Claims 15-17, 21, 22, 23, 26-30, 33, and 34 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Lazarowych et al. (WO 96/22774), the Product Alert Bulletin regarding Alvita Herbal RemeTeas (22 July 1996 - PROMT Abstract), Marles et al. (J. Nat. Prod., 1992), and the admitted state of the art, for the reasons set forth in the previous Office action, which are restated below.

Lazarowych et al. teach the treatment of migraines using an herbal composition comprising *Tanacetum parthenium* and which may also contain ginger for such purpose. (see, e.g., pages 1-6).

The Product Alert Bulletin discloses a commercial product from Alvita Herbal RemeTeas called Migra-Wonder™ which comprises feverfew and ginger and which, as the name clearly implies, is used to treat headaches including migraine headaches (see abstract).

Marles et al. disclose that it is well known in the art that *Tanacetum parthenium* preparations, containing a result-effective content of the active ingredient parthenolide therein, are well known in the herbal art for treating and preventing migraine headaches (see, e.g., pages 1044-1045). Marles et al. also disclose it is well known in the herbal art that *Zingiber officinale* (ginger) is traditionally used for treating and preventing migraines (see, e.g., paragraph bridging pages 1046-1047).

In addition, as readily admitted by applicant, *Tanacetum parthenium* is well known in the herbal art (feverfew) to be useful for treating and preventing migraines (see, e.g., page 4, first full paragraph of the instant specification). Further, as readily admitted by applicant, most migraine sufferers are women and they are most likely to suffer a migraine during their menstrual periods (see, e.g., the last six lines on page 3 of the instant specification).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine *Tanacetum parthenium* and *Zingiber officinale* for their known benefit in treating and/or preventing migraine headaches (including in a menstruating woman suffering from a migraine), since each is well known in the art for their claimed purpose and for the following reason. It is well known that it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Sussman,* 1943 C.D. 518; *In re Pinten*, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074,

1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Thus, the invention as a whole is clearly *prima facie* obvious over the references, especially in the absence of clear, convincing, and sufficient evidence to the contrary.

Claims 15-40 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Wyandt et al. (Drug Topics, June 98 - PROMT Abstract), Castleman (The Healing Herbs, 1991), Marles et al. (J. Nat. Prod., 1992), the PDR for Herbal Medicines (published Spring 1998), Popp (EP 248215 - DWPI Abstract), and the admitted state of the art, in view of Thys-Jacobs (US 5,443,850), for the reasons set forth in the previous Office action which are restated below.

Wyandt et al. disclose that feverfew (aka *Tanacetum parthenium*) has a long history of use in traditional and folk medicine as a treatment for menstrual irregularities as well as, more recently, as a treatment for migraine headaches (see abstract).

Castleman teaches that ginger (*Zingiber officinale*) is well known in the art to have traditional use in women's health for treating menstrual cramps and gynecological problems, as well as a digestive aid in relieving gastrointestinal distress (see, e.g., pages 187-188). Marles teaches that ginger is also well known in the art to have traditional use in treating and preventing migraines (see, e.g., paragraph bridging pages 1046-1047).

The PDR for Herbal Medicines reference teaches that *Cimicifuga racemosa* (black cohosh) and *Vitex agnus-castus* (chaste tree) are well known in the art to be useful in treating menstrual/premenstrual disorders (see heading *Indications and Usage* for both plants). In addition, as readily admitted by applicant, it is well known in the herbal art that *Tanacetum parthenium* is useful for treating and preventing migraines (see, e.g., page 4, first full paragraph of the instant specification), and that *Vitex agnus-castus* and *Cimicifuga racemosa* are both useful in treating premenstrual disorders (see, e.g., pages 5-6 of the instant specification). Further, as readily admitted by applicant, most migraine sufferers are women and they are most likely to suffer a migraine during their menstrual periods (see, e.g., the last six lines on page 3 of the instant specification). Also, as disclosed by Thys-Jacobs, seventy percent of women who suffer migraines report a significant proportion of attacks during their premenstrual period (see, e.g., col 1, lines 22-49).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known beneficial uses since each is well known in the art for such uses (i.e., to treat migraines as well as menstrual/premenstrual disorders, especially since women are the predominant sufferers of migraines and suffer migraines most often during their menstrual/premenstrual periods) and for the following reasons. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman,* 1943 C.D. 518; *In re Pinten*, 459 F.2d

1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of clear, convincing, and sufficient evidence to the contrary.

Applicants' previous arguments with respect to the U.S.C. 103 rejections above have been carefully considered but are not deemed to be persuasive of error in the rejections. As discussed above, Applicants appear to argue that Product Alert Bulletin does not necessarily teach a preparation comprising a combination of *Tanacetum parthenium* (feverfew) and one of the other claimed components (i.e., *Zingiber officinale* - aka ginger), and that applicants request that examiner make of record the entirety of this article. However, this full-text enabled abstract expressly teaches such a combination as an anti-migraine preparation. Applicants further argue that Lazarowych et al. teach that their compositions containing *Tanacetum parthenium* - parthenolide lactone may additionally include other active ingredients (from a listing of 34), however the reference never discloses which of those ingredients should be used in combination with the parthenolide lactone from *Tanacetum parthenium*. However, Lazarowych et al. clearly disclose to the skilled artisan that *Tanacetum parthenium* (comprising the bioactive lactone - parthenolide) can beneficially be combined with ginger for the therapeutic effects disclosed therein.

In addition, with respect to Applicants' previous arguments over the U.S.C. 103 rejections above, Applicants have argued and discussed the various cited references individually without clearly addressing the combined teachings. It must be remembered that the references are relied upon in combination and are not meant to be considered separately as in a vacuum. It is the combination of all of the cited and relied upon references which make up the state of the art with regard to the claimed invention. Applicant's claimed invention fails to patentably distinguish over the state of the art represented by the references. Further, please note that based upon the teachings of the cited art as a whole (including, e.g., for treating various conditions such as menstrual disorders, irregularities, cramps, and/or potential migraines commonly associated therewith) the administration of two or more of the claimed plant components for their known benefit(s) - as discussed *supra* - would intrinsically prevent migraines from occurring.

It is reemphasized that Applicants invention is predicated on an unexpected result, which typically involves synergism, an unpredictable phenomenon, highly dependent upon specific proportions and/or amounts of particular ingredients (i.e., operative amounts and/or ratios of each of the two or more active ingredients therein, not just one - as instantly claimed, e.g., in claims 23-26, 30-33, and 35-40). Any mixture of the components embraced by the claims which does not exhibit an unexpected result (e.g., synergism) is therefore *ipso facto* unpatentable.

Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him, with respect to each of the U.S.C. 103 rejections set forth above.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (703) 305-7114. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached at (703) 306-3220. The Group receptionist may be reached at (703) 308-0196. The fax number for art unit 1654 is (703) 872-9306.

Please note that as of January 20, 2004, the examiner's telephone number is being changed to (571) 272-0970 and the supervisor's telephone number is being changed to (571) 272-0961.

Christopher R. Tate
Primary Examiner, Group 1654